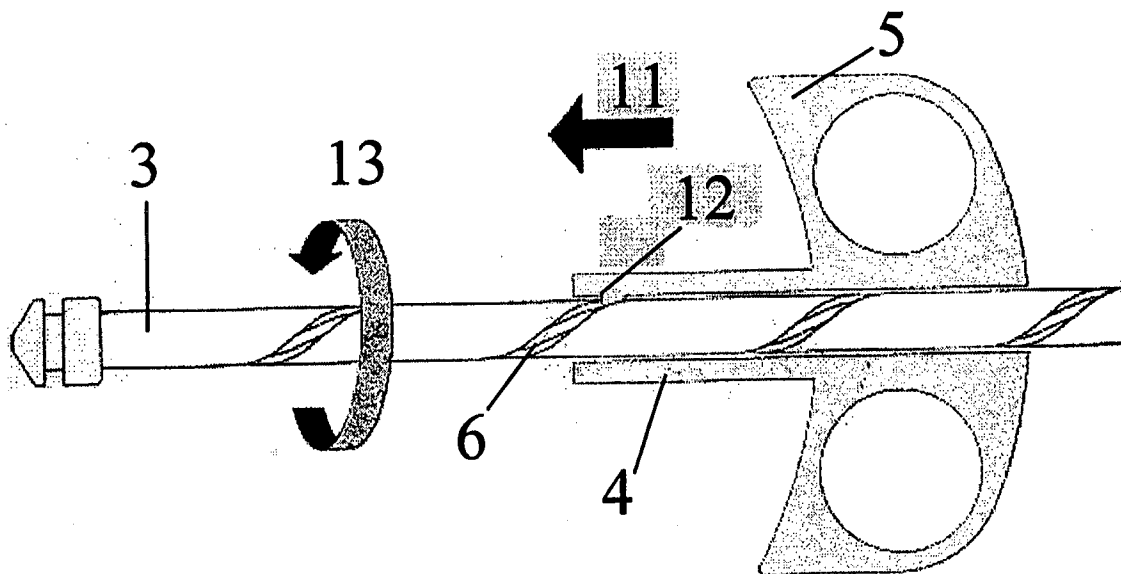


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61F 2/06	A1	(11) International Publication Number: WO 98/52496 (43) International Publication Date: 26 November 1998 (26.11.98)
(21) International Application Number: PCT/GB98/01440 (22) International Filing Date: 19 May 1998 (19.05.98) (30) Priority Data: 9710366.7 20 May 1997 (20.05.97) GB (71) Applicant (for all designated States except US): BIOCOMPATIBLES LIMITED [GB/GB]; Frensham House, Farnham Business Park, Weydon Lane, Farnham, Surrey GU9 8QL (GB). (72) Inventors; and (75) Inventors/Applicants (for US only): LAW, Brian, Robert [GB/GB]; 11 Meadhurst Road, Leicester LE3 6FR (GB). BARTLETT, Jeremy [GB/GB]; Biocompatibles Ltd., Frensham House, Farnham Business Park, Weydon Lane, Farnham, Surrey GU9 8QL (GB). WOODROFFE, Matthew, John [GB/GB]; Biocompatibles Ltd., Frensham House, Farnham Business Park, Weydon Lane, Farnham, Surrey GU9 8QL (GB). STRATFORD, Peter, William [GB/GB]; Biocompatibles Ltd., Frensham House, Farnham Business Park, Weydon Lane, Farnham, Surrey GU9 8QL (GB). TARIAH, Ibim [GB/GB]; Biocompatibles Ltd., Frensham House, Farnham Business Park, Weydon Lane, Farnham, Surrey GU9 8QL (GB). TAYLOR, Alistair,		Stewart [GB/GB]; Biocompatibles Ltd., Frensham House, Farnham Business Park, Weydon Lane, Farnham, Surrey GU9 8QL (GB). YIANNI, Yiannakis, Petrou [GB/GB]; Biocompatibles Ltd., Frensham House, Farnham Business Park, Weydon Lane, Farnham, Surrey GU9 8QL (GB). (74) Agent: GILL JENNINGS & EVERY; Broadgate House, 7 Eldon Street, London EC2M 7LH (GB). (81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>

(54) Title: STENT DEPLOYMENT DEVICE**(57) Abstract**

A device/stent combination comprises a delivery device for delivery of a self expanding braided stent comprising a distal end section, a proximal end section and a flexible elongate body joining the two ends, in which the distal end section has a stent retaining means comprising a sleeve, a core and a gripper which grips one end of the stent between the sleeve and the core and prevents axial movement of the stent relative to the core. The proximal end comprises a handle and trigger for actuating deployment and a stent mounted for deployment.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

STENT DEPLOYMENT DEVICE

The present invention relates to a delivery device for a self expanding stent whose length shortens upon delivery from a small diameter to an expanded diameter conformation, which comprises a compensation mechanism which shifts the undelivered end of the stent towards the delivered portion by an amount adequate to compensate for the shortening and minimise displacement of the stent against the vessel wall.

Surgical dilators comprising a braided device whose diameter can be expanded by shortening the axial length are known. An early description of such a device for use in *inter alia*, the oesophagus, is provided in GB-A-1205743. In WO-A-8303752 Wallsten described a prosthetic implant, primarily for use in blood vessels, which comprises a braided tube, called a stent. The tube is braided such that it is biased towards a radially expanded position and can be held for delivery in a radially compressed, loaded position for transluminal delivery. Wallsten describes two main types of delivery device. One has retention means for both ends of the stent, which, in the delivery conformation, retain the stent by exerting axially directed opposing forces operating to pull the ends of the stent away from each other. The stent is delivered by moving the proximal stent end retaining mechanism towards the distal end and allowing the central portion of the stent to expand outwards to contact the inner wall of the vessel in which it is to be implanted. Once the whole of the body portion is deployed the ends of the stent are released. The drawing shows that the length change during deployment, whilst the distal end of the stent remains in fixed position relative to the vessel, results in inevitable displacement of the central deployed section in the blood vessel causing potential trauma to the vessel wall.

A second delivery device illustrated in Wallsten's original specification comprises a sleeve within which the stent is retained in its delivery conformation. A pusher

tube is provided which abuts the proximal end of the stent and pushes the stent out from the distal end of the sleeve.

In order to prevent the distal, expanded end of the stent being pushed along the inside of the vessel during delivery it is necessary to withdraw the sleeve proximally whilst pushing the pusher in the distal direction. Coordinating the movements generally requires the use of both of the surgeon's hands and it is always difficult to coordinate the relative movements so as to avoid any movement of the deployed end of the stent relative to the blood vessel. Whilst Wallsten suggests that the relative motion between the sleeve and the pusher may be controlled mechanically, he does not disclose how such control might be achieved.

In a later published specification US-A-4,732,152, Wallsten et al describe a "rolling membrane" delivery device. A tubular membrane is folded over on itself to provide a double walled tube in the inner lumen of which the stent is retained in its reduced diameter conformation. When the outer wall is moved proximally the fold at the distal end travels proximally to allow the stent to expand from the distal end. This device suffers the same disadvantages as the original delivery devices, in that the proximal end remains in fixed position relative to the vessel, thereby requiring that the deployed distal end withdraw towards the proximal end as the diameter expands and the length shortens. Alternatively the surgeon must attempt to move the inner member joined to the inner wall of the membrane to move distally by a compensating amount. Another problem, common to this device and the second of Wallsten's original delivery devices, is that the stent cannot be retracted into the delivery device after partial deployment for instance upon the surgeon's requiring repositioning of the device.

The problems of US-A-4,732,152 were said to be solved in US-A-5,201,757 by providing two sleeve portions, a proximal sleeve portion surrounding the proximal half of

the stent and the distal sleeve portion surrounding the distal end of the stent. The sleeves may simultaneously be withdrawn from the centre of the stent towards the respective ends to allow deployment from the centre. Means
5 are provided for retaining the stent centre in fixed position relative to the blood vessel during deployment either comprising a central catheter located between the internal catheter joined to the distal sleeve portion and the external catheter joined to the proximal sleeve
10 portion, which central catheter has means for preventing axial movement of the stent but allowing relative axial movement of both internal and external catheters. Another mechanism comprises an internal catheter provided with external screw threads at each end of the stent retention
15 section. Each set of threads engage with internal threads on respective sleeve carriers. The rotation of the sleeve carriers relative to the internal catheter is prevented. Rotation of the internal catheter thus results in movement of both sleeve carriers by the same amount, so that, by
20 keeping the internal catheter fixed axially relative to the blood vessel and rotating it, the sleeves can both be removed by the same amount from respective ends of the stent. It is, however, easier for deployment to involve axial movement rather than rotational movement.

25 According to the present invention there is provided a device/stent combination comprising a delivery device for delivery of a self expanding braided stent comprising a distal end section, a proximal end section and a flexible elongate body joining the two ends, in which the distal end
30 section has a stent retaining means comprising a sleeve, a core and a gripper which grips one end of the stent between the sleeve and the core and prevents axial movement of the stent relative to the core, and in which the proximal end comprises a handle and trigger for actuating deployment and
35 a stent mounted for deployment, wherein the stent is formed of braided counter rotating helical filaments, of which at least some of the filaments are welded at or near the stent

ends at crossover points, whereby blobs of resolidified welded material are formed at welded crossover points and in which the gripper holds the stent between the sleeve and the core and prevents axial movement of the stent end relative to the core in the direction in which the sleeve moves during deployment and in the opposite direction and in which the gripper comprises a circumferential slot around the external periphery of the core having axially directed shoulders for engaging the blobs of welded material at the stent end whereby the stent can be partially deployed by withdrawal of the sleeve and then retracted back into the sleeve by withdrawing the core to allow repositioning of the stent.

A further delivery device according to the invention for delivery of a self expanding braided stent comprises a distal end section, a proximal end section and a flexible elongate body joining the two ends, in which the distal end section has a stent retaining means comprising a sleeve, a core and a gripper which grips one end of the stent between the sleeve and the core and prevents axial movement of the stent relative to the core, and in which the proximal end comprises a handle, a housing having a trigger, which housing can be moved axially relative to the handle, a pusher which is rotationally fixed relative to handle and a compensating sleeve fixed axially relative to the handle and having two sets of screw threads one of which threadedly engages co-operating means on the pusher, and the other of which threadedly engages co-operating means provided on the pusher, whereby upon relative axial movement of the handle and the housing the compensating sleeve is caused to rotate relative to the handle, which causes the pusher to move axially relative to the handle in the opposite direction to the housing, the pusher being operatively connected to one of the core and the sleeve and the housing being operatively connected to the other of the core and the sleeve whereby upon axial movement of the pusher and the housing, the sleeve is withdrawn from a

first end of the stent and the core is moved in the opposite direction whereby the first end of the stent is axially stationary relative to the handle during deployment.

5 Preferably the pusher is attached to the core, for instance by forming the pusher and core from a single tubular member.

 Preferably the sleeve is joined to the housing for instance by an external catheter tube extending the entire
10 length of the deployment device. The catheter tube may have a separate lumen for delivery of liquid, for instance contrast liquid to allow visualisation of the implantation site by X-rays during the surgical procedure, or medicaments. Such a separate lumen is provided with liquid
15 inlet at the proximal end of the device. Alternatively the single lumen of an external catheter tube may provide a contrast liquid or medicament liquid conduit and may thus be provided with a liquid inlet and a seal for sealing the lumen proximally of the liquid inlet.

20 The means for fixing the pusher rotationally with respect to the handle may comprise a tongue extending along the axis of the handle and slidably received in a slot in the inside of the proximal wall of the hollow handle.

 Preferably the housing is tubular and slides inside
25 the hollow handle. Mutual rotation between the housing and the handle may be prevented for instance by providing a peg on one opposing surface and a slot parallel to the axis within which the peg can slide. The trigger attached to the housing is for gripping of the housing and preferably
30 comprises a ring for a finger grip.

 The compensating sleeve is preferably provided with screw threads in its inner wall which threadedly engage co-operating means, preferably a screw thread on the outside of a pusher which passes through the sleeve. The sleeve
35 preferably has screw threads in its outer wall, which threadedly engage co-operating means on the inner wall of the housing. The co-operating means may be a screw thread

or a peg which slides in the helical screw thread on the compensating sleeve.

By selection of appropriate handedness for the screw thread on the compensating sleeve the desired direction of movement of the pusher and the housing is obtained. By selection of appropriate pitch for each of the screw threads the relative distances moved for the housing and the pusher relative to the handle is controlled.

The combination of the present invention allows retention of the stent during deployment so that its position can be adjusted prior to full expansion and so that the stent can be withdrawn back into the deployment device if an operator decides that its current location is not appropriate.

The deployment device allows deployment of a stent from inside the sleeve from one stent end. As the sleeve is withdrawn towards the other end of the stent, that other end is moved in the opposite direction by the core whereby the change in axial length upon deployment is compensated to minimise movement of the deployed end of the stent against the inner wall of the vessel in which the stent is being deployed. The degree of compensation is preset by reference to the expected axial shortening of the stent in the vessel into which implantation is desired.

The deployment device is preferably for use with a stent formed of braided counter rotating helical filaments, preferably with at least 8 filaments being wound in each direction, of which at least some of the filaments are welded at or near the stent ends at crossover points, whereby blobs of resolidified welded material are formed at welded crossover points. These blobs form a general thickening of the walls. A stent of this type is described further in our co-pending application no. PCT/GB96/02689.

The gripper which holds the stent between the sleeve and the core should prevent axial movement of the stent end relative to the core at least in the direction in which the sleeve moves during deployment. This results in the stent

end being moved with the core in the opposite direction to the sleeve during deployment. Preferably axial movement in the opposite direction relative to the core is also prevented by the gripper. This may allow the retraction of the stent back into the sleeve before full deployment by reverse movement of housing and handle, where the sleeve is sufficiently stiff to allow such retraction during which the stent must be radially compressed as it is retracted into the sleeve.

Where the stent is a welded end helical stent, the gripper may comprise a circumferential slot around the external periphery of the core having axially directed shoulders for engaging the blobs of welded material at the stent end. The space between the sleeve and the core inboard (with respect to the stent) from the slot is large enough to house the stent in its radially compressed form, but not large enough for the blobs of material at the welded stent end. The sleeve is preferably provided with a lubricious internal wall whereby the sleeve can slide relative to the stent. Alternatively the sleeve may be of the rolling membrane type as described in US-A-4,732,152 so that sliding of the sleeve relative to the stent is unnecessary. With such membranes, however retraction of a partially deployed stent is difficult or impossible.

Where the device allows retraction after partial deployment it is preferred for the proximal end of the device to have a visual or mechanical indication of the extent of deployment beyond which retraction is no longer possible. The surgeon can thus ensure that proper positioning of the device is achieved. Preferably the indication is a mechanical step which stops relative movement of the handle and housing beyond that extent of deployment. The step should be releasable to allow further relative movement beyond the said extent and allow complete withdrawal of the stent from the sleeve and full deployment.

The core may extend just beyond the proximal end of the stent. Preferably however it extends through the inside of the stent up to and optionally beyond the distal end. Generally the core has an inner lumen through which
5 a guide wire may pass where the core extends through the whole stent, snagging of the guide wire on the internal wall of the stent during surgery is prevented.

The deployment device may be used by being delivered "over the wire" or as a rapid exchange type device. An
10 over the wire device has a guide wire lumen extending along the whole length of the device, axially through the stent at the distal end and out at the proximal end. Where the pusher and core are formed of a single inner tube the inner lumen of such a tube may conveniently form the guide wire
15 lumen. Preferably the guide wire exits through the proximal end wall of the handle.

A device for use in a rapid exchange system has a shorter guide wire lumen extending through the stent and exiting the device proximally of the stent retention
20 section. Where the guide wire lumen is provided through the inside of an internal catheter tube forming the core and the core slides axially inside an external catheter tube, the exit from the device must allow for this sliding and thus comprises an axial slot in at least one of the
25 inner and outer catheter tubes, co-operating with a hole or a slot in the other. Means for allowing a guidewire to be threaded through the lumen and out of the exit should be provided for instance as a plug with an appropriately shaped surface for directing the guide wire end located in
30 the lumen of the inner catheter of the exit.

The device may be provided with radiopaque markers for visualisation during deployment. For instance, the core may have a marker level with the second end of the stent, which thus moves during deployment with the second stent
35 end (last to be deployed). Preferably a marker is provided level with the first end of the stent in the delivery conformation, which can thus be positioned at the desired

location in a blood vessel. Alternatively, or additionally, the stent to be delivered may have radiopaque markers at each end and/or at an intermediate position along its length.

5 The present invention provides also a combination of a deployment device and a braided stent loaded in the device for deployment, as well as a method in which the device is used to deploy a braided stent. Although the stent has been described with reference to a prosthesis for
10 holding open a blood vessel, it may also be a vascular graft, for repairing damages or leaky vessels, or may be an oesophageal dilator, or a urethral stent.

The invention is described further with reference to the following drawings in which:

15 Figure 1 shows a side view of the compensation sleeve and housing and trigger of the, preferred embodiment of the delivery device;

Figure 2 shows a cross section through the compensation sleeve and pusher of the preferred embodiment
20 of the delivery device;

Figure 3 shows a horizontal section through the proximal end of another embodiment of the delivery device prior to deployment of a stent;

Figure 4 shows a vertical section corresponding to the device of Figure 3;
25

Figure 5 shows a horizontal section through proximal end of the device of figure 3 with the stent deployed to the furthest position up to which retraction is possible;

Figure 6 shows the vertical section corresponding to
30 Figure 5;

Figure 7 shows an enlarged view of the distal end of Figure 5;

Figure 8 shows the device of Figure 7 in the fully deployed condition, after release of the end stop;

35 Figure 9 shows a horizontal section through the trigger portion and associated portions of the device of Figure 3;

Figure 10 shows a centre line section through a portion of the distal end of the device and proximal end of the stent;

Figure 11 shows a radial section along line XI -XI of Figure 10;

Figure 12 shows a centre line section through the body section of a device at the guide wire exit before stent deployment; and

Figure 13 shows the section corresponding to that of Figure 12 after stent deployment.

Referring to Figure 1, there is shown an external view of a compensation sleeve 3 and a housing 4 and trigger 5. Compensation sleeve 3 has an external screw thread 6 (in this left handed) in which slides a peg 12 located on the inside of housing 4. As the trigger 5 is moved with housing 4 in the direction shown by arrow 11 (proximally), the compensation sleeve is caused to rotate in the direction shown by arrow 13 (counterclockwise viewed from the proximal (left hand in the drawing) end).

As shown in Figure 2 rotation of compensation sleeve 3 in the direction of arrow 13 causes the pusher 7, which has external screw threads 8 which co-operate with internal screw threads 14 on the compensation sleeve 3, to move in the distal direction as shown by arrow 23. The relative amount of proximal movement of housing 4 and distal movement of pusher 7 is controlled by the relative pitches of screw threads 6 and 14.

As shown in Figure 3, the proximal end of a deployment device comprises a handle 2, having a proximal end wall 10, in which slides a housing 4 connected to trigger 5 which has two finger holes. Within the inner lumen of housing 4 is a compensation sleeve. In this embodiment the housing 4 extends distally beyond the distal end of the compensation sleeve 3, but it includes a peg similar to peg 12 of Figure 1 which slides in an external screw thread in the compensation sleeve. Rotation of handle 2 and housing 4 is prevented by a peg 15 on the inner wall of the handle

which slides in axial slot 16 in the outer wall of housing 4. Axial movement of sleeve 3 relative to the handle 2 is prevented by co-operating circumferential slot 17 in the outer wall of the sleeve 3 at its proximal end and a peg 18 in the internal wall of the handle 2.

Through the inside of sleeve 3 a pusher 7 extends. At the proximal end of pusher 7 there is a tongue 19 which is flattened horizontally and is received in a slot 20 in the proximal wall 10 of the handle. In the pre-deployment condition, the tongue is located at the extreme proximal position.

The handle 2 is further provided with an end stop 21 which has a button 22, the function of which is explained further below with reference to Figures 7 and 8. The housing 4 is further provided at its distal end with contrast liquid inlet 25, and seal 26, providing a conduit for contrast liquid or medicament into the lumen between the core 27 which is fixed to pusher 7 and the external catheter 28 which is fixed to the distal end of housing 4, the exit of the conduit being towards the distal end of the device.

As shown in Figures 5, 6, 7 and 8 to deploy a stent, the trigger 5 and housing 4 are pulled proximally so that the housing slides in the handle, causing the compensation sleeve 3 to rotate and pusher 7 to move in a distal direction. The extent of movement of housing 4 is provided by end stop 21 which abuts the proximal end 29 of housing 4. This indicates the extent of deployment of the stent at the distal end of the device beyond which refraction for repositioning cannot take place. Having deployed the stent to this extent, once the surgeon is sure the positioning is correct, end stop 21 can be released by pushing button 22 inwards, pivoting end stop about pivot 30. Thus the end stop 21 is released from abutment with the proximal end 29 of the housing 4 and housing 4 can be moved further proximally to release the stent from the device completely, by retracting the sleeve beyond the proximal end of the

stent. Figures 7 and 8 show that the pusher 7 has moved distally relative to the housing by 14 mm, with proximal movement of 102 mm of the housing.

Figure 9 illustrates the distal end portion of housing 4 and shows the pusher 7 extending through the housing and joined beyond the housing to a tubular section 31 which becomes, at the distal end of the device, the core. A sheath or external catheter 28 is fixed to the distal end 32 of housing 4. A liquid inlet port 25 is located in the wall of the housing 4 beyond the finger grips 5. A seal 26 provides a liquid tight seal between the housing 4 and the pusher 7 whereby liquid introduced through the port 25 passes along the conduit between sheath 28 and the tubular section of pusher/core 31 towards the distal end of the device. Contrast fluid for X-ray visualisation of the site of surgery may be introduced through this port and conduit and/or liquid medicament, for instance anti-thrombogenic agents or anti-convulsive agents.

Figure 10 illustrates the proximal portion of the distal, stent retaining portion of a deployment device for a welded end stent 33. The stent has weld beads (blobs) 34 at the proximal end, which are retained by an interference fit in a circumferential slot 35 with a conical section outer surface 37 in a delivery component 36 joined to the end of the internal catheter which forms core 31. Retention of the weld beads in the slot 35 is assisted by a conical silicone tube 38 having a distally directed external stent pushing shoulder 39. The delivery component 36 is joined to a helical spring 40 which extends distally from the delivery component 36 internally of the stent 33. The spring 40 helps optimise axial flexibility of the portion of the device where the stent is located. The spring 40 also provides part of the guide wire lumen and protects the inner surface of the stent 33 from contact with and damage by the guide wire.

Upon proximal movement of the housing 4 sheath 28 will be withdrawn, releasing the distal end of the stent 33 and

allowing it to self-expand against the wall of the vessel in which it is to be implanted. As the sheath 28 is pulled further back sliding past the stent 33 and the delivery component 36 and the stent is further deployed, whereby it becomes axially shortened, the core comprising delivery component 36 is moved distally which results in conical silicone tube 38 abutting against the proximal end of the slot 5 in the component 36, whereby the proximal end of the stent is pushed distally by an amount to compensate for the axial shortening.

If repositioning of the stent is desired before full deployment the sheath 28 can be pushed distally by movement of the housing 4 distally with respect to the handle 2, which causes a corresponding movement of the core 36 in a proximal direction causing the sheath (sleeve) 28 to be pushed back over the stent. The proximal stent end is held axially with respect to the core 36 between the conical silicone tube 38 which moves proximally with the core 36.

Figure 11 shows a section along line XI - XI of Figure 10. Stent weld beads 34 are retained between the sheath (sleeve) 28, in this case a 2.33 mm outer diameter catheter with a 0.2 mm wall thickness, and the silicone tube 38 located in circumferential slot in delivery component 36 (omitted for clarity). A guide wire 41 is shown passing through the inner spring 40 located internally of the stent.

A preferred embodiment of the device is provided with means enabling it to be delivered by rapid exchange techniques. As shown in Figure 12, which illustrates a section through a part of the body section of the device located a few centimetres proximally from the distal section illustrated in Figure 10, a guide wire 41 passes through the lumen 42 inside a tubular core/pusher catheter 31. A wall 43 blocks the inner lumen and a hole 44 is formed in the wall of the internal catheter 31 through which the guide wire 41 exits. A slot 45 is formed in the wall of the outer catheter or sheath 28, which is aligned

with the hole 44, and is at least as long 53 as the distance the housing 4 can move with respect to the pusher 7. Figure 12 shows the relative positions of the core 31, sheath 28 and guide wire 41 in the pre-deployment position (the proximal direction being towards the left of the drawing). Figure 13 shows the corresponding positions at the complete deployment position in which the core and the sheath have moved axially with respect to one another.

The stent illustrated expands from a diameter of 2 mm to a diameter of 8 mm with a corresponding length reduction of 14 mm to a final length of 100 mm. The handle 2 is preferably moulded from a plastics material. The compensation sleeve 3 is preferably moulded from a plastics material. The compensation sleeve 3 is preferably machined from stainless steel. The pusher and core are preferably formed of stainless steel.

CLAIMS

1. A device/stent combination comprising a delivery device for delivery of a self expanding braided stent comprising a distal end section, a proximal end section and a flexible elongate body joining the two ends, in which the distal end section has a stent retaining means comprising a sleeve, a core and a gripper which grips one end of the stent between the sleeve and the core and prevents axial movement of the stent relative to the core, and in which the proximal end comprises a handle and trigger for actuating deployment and a stent mounted for deployment, wherein the stent is formed of braided counter rotating helical filaments, of which at least some of the filaments are welded at or near the stent ends at crossover points, whereby blobs of resolidified welded material are formed at welded crossover points and in which the gripper holds the stent between the sleeve and the core and prevents axial movement of the stent end relative to the core in the direction in which the sleeve moves during deployment and in the opposite direction and in which the gripper comprises a circumferential slot around the external periphery of the core having axially directed shoulders for engaging the blobs of welded material at the stent end whereby the stent can be partially deployed by withdrawal of the sleeve and then retracted back into the sleeve by withdrawing the core to allow repositioning of the stent.

2. A delivery device for delivery of a self expanding braided stent comprising a distal end section, a proximal end section and a flexible elongate body joining the two ends, in which the distal end section has a stent retaining means comprising a sleeve, a core and a gripper which grips one end of the stent between the sleeve and the core and prevents axial movement of the stent relative to the core, and in which the proximal end comprises a handle, a housing having a trigger, which housing can be moved axially

relative to the handle, a pusher which is rotationally fixed relative to handle and a compensating sleeve fixed axially relative to the handle and having two sets of screw threads one of which threadedly engages co-operating means
5 on the pusher, and the other of which threadedly engages co-operating means provided on the pusher, whereby upon relative axial movement of the handle and the housing the compensating sleeve is caused to rotate relative to the handle, which causes the pusher to move axially relative to
10 the handle in the opposite direction to the housing, the pusher being operatively connected to one of the core and the sleeve and the housing being operatively connected to the other of the core and the sleeve whereby upon axial movement of the pusher and the housing, the sleeve is
15 withdrawn from a first end of the stent and the core is moved in the opposite direction whereby the first end of the stent is axially stationary relative to the handle during deployment.

20 3. A device according to claim 2 in which the pusher is attached to the core, by forming the pusher and core from a single tubular member.

25 4. A device according to claim 2 or claim 3 in which the sleeve is joined to the housing by an external catheter tube extending the entire length of the deployment device.

30 5. A device according to any of claims 2 to 4 which comprises a liquid inlet for introduction of contrast fluid at the proximal end of the device into a conduit for outflow at or near the distal end of the device.

35 6. A device according to any of claims 2 to 5 in which the means for fixing the pusher rotationally with respect to the handle comprises a tongue extending along the axis of the handle and slidably received in a slot in the inside of the proximal wall of the hollow handle.

7. A device according to any of claims 2 to 6 in which the compensating sleeve is provided with screw threads in its inner wall which threadedly engage co-operating means, preferably a screw thread on the outside of a pusher which passes through the sleeve.

8. A device according to claim 7 in which the sleeve has screw threads in its outer wall, which threadedly engage co-operating means on the inner wall of the housing.

9. A device according to any of claims 2 to 8 in which the core carries a radiopaque marker level with the proximal end of the stent.

10. A device according to any of claims 2 to 9 in which the core extends beyond the distal end of the stent position and has a guidewire lumen for passage of a guidewire through the stent before and after deployment.

11. A device/stent combination comprising a device according to any of claims 2 to 10 having a stent mounted for deployment, wherein the stent is formed of braided counter rotating helical filaments, of which at least some of the filaments are welded at or near the stent ends at crossover points, whereby blobs of resolidified welded material are formed at welded crossover points.

12. A device stent combination according to claim 10 in which the gripper holds the stent between the sleeve and the core and prevents axial movement of the stent end relative to the core at least in the direction in which the sleeve moves during deployment.

13. A combination according to claim 12 in which axial movement in the opposite direction relative to the core is also prevented by the gripper.

14. A device stent combination according to claim 12 or claim 13 in which the gripper comprises a circumferential slot around the external periphery of the core having axially directed shoulders for engaging the blobs of welded material at the stent end.

15. A stent deployment method in which a device stent combination according to claim 1 or 11 to 14 is delivered transluminally through a blood vessel on a guidewire and in which the stent is deployed at the desired site by mutual sliding movement of the handle and trigger to release the stent from the stent retaining means.

1/7

Figure 1

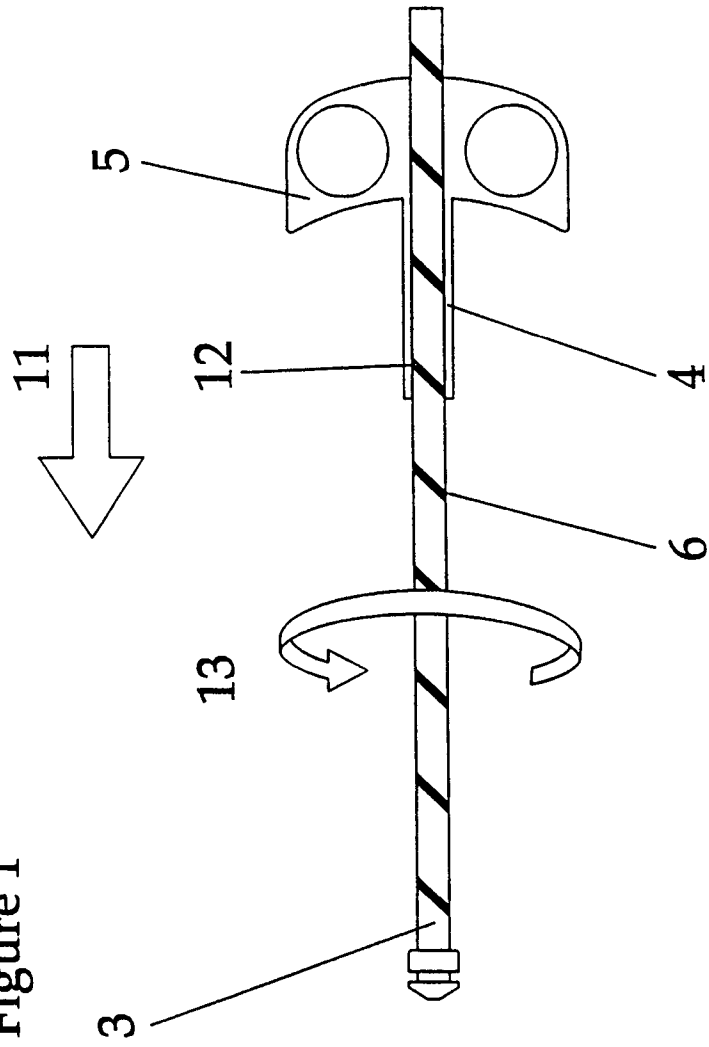


Figure 2

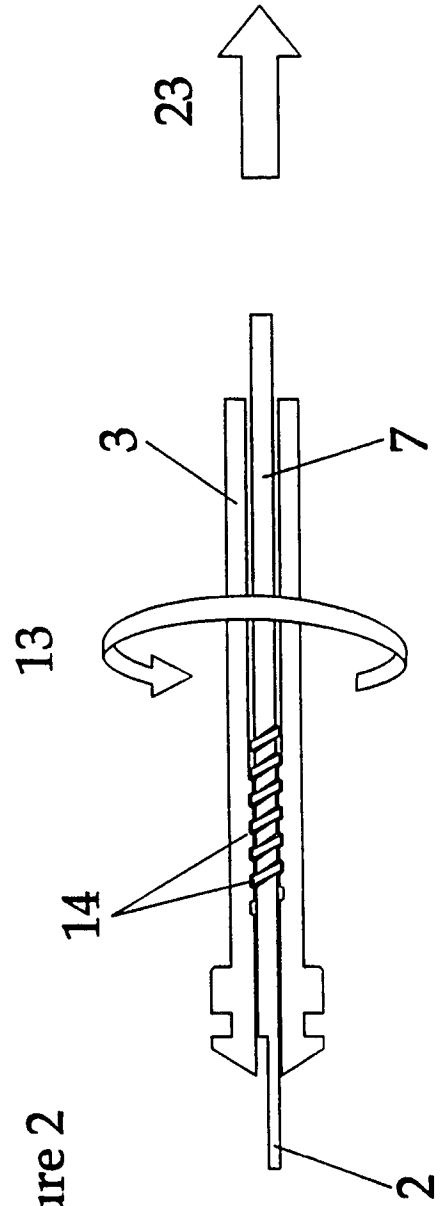
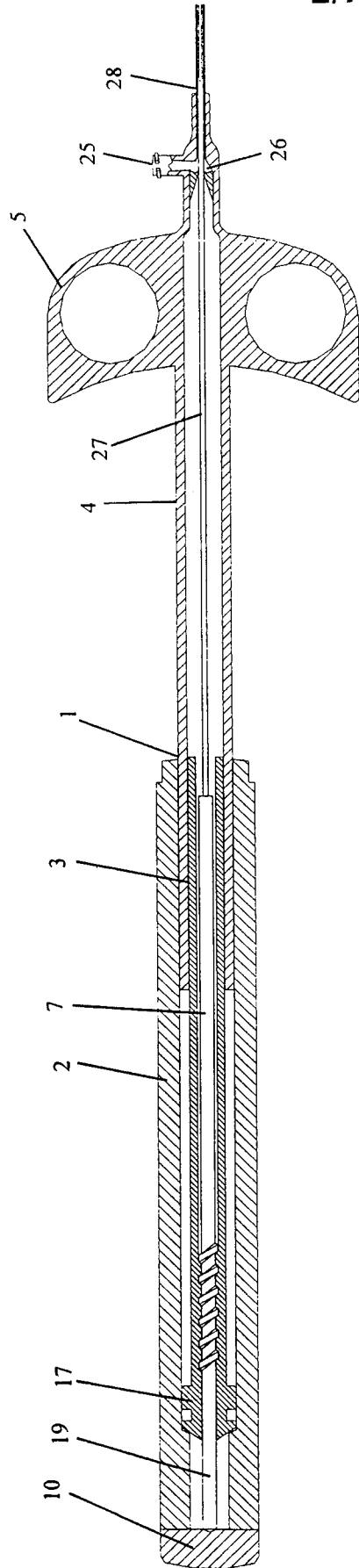


Figure 3



2/7

Figure 4

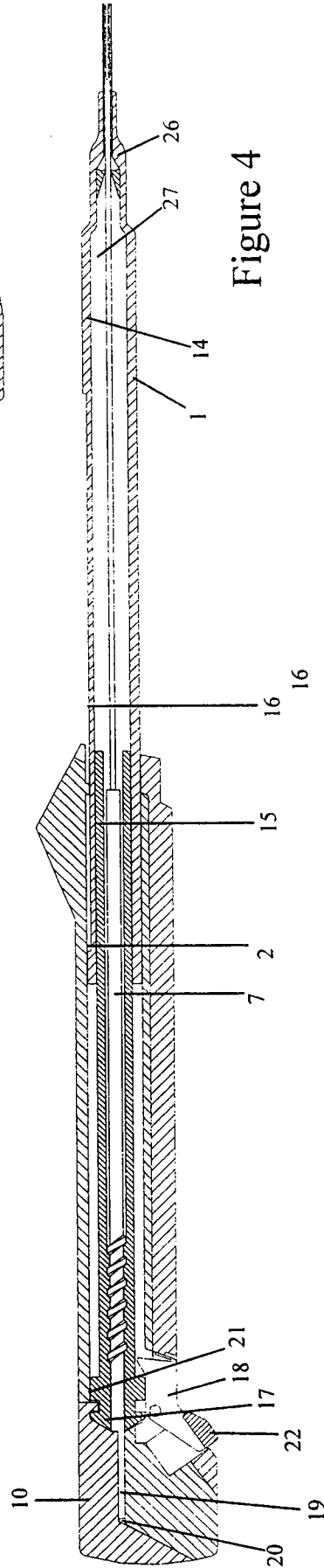
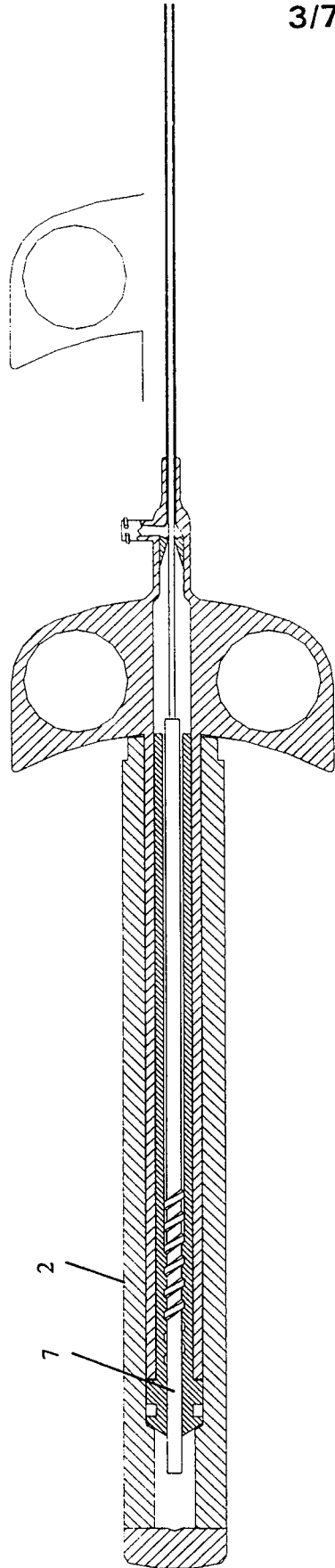


Figure 5



3/7

Figure 6

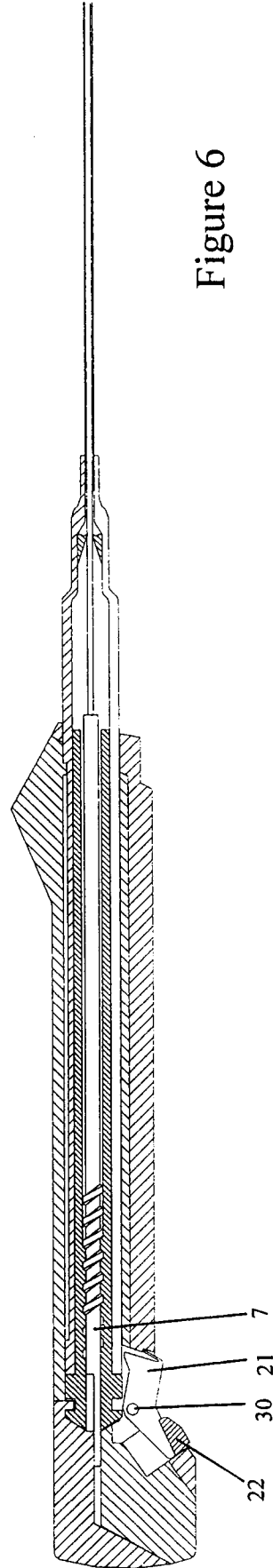
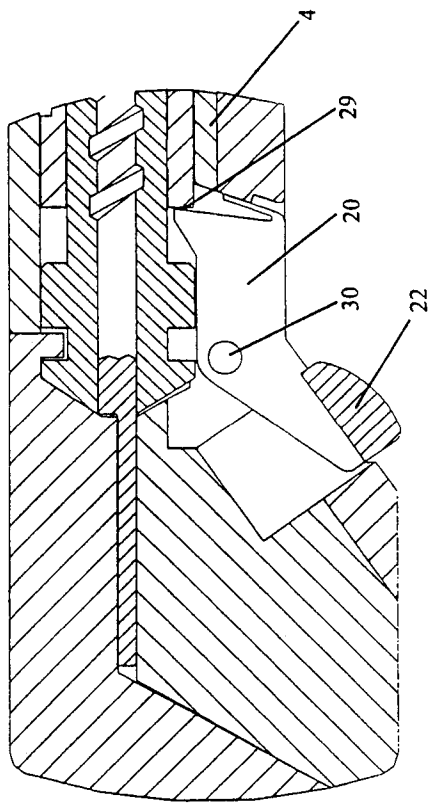
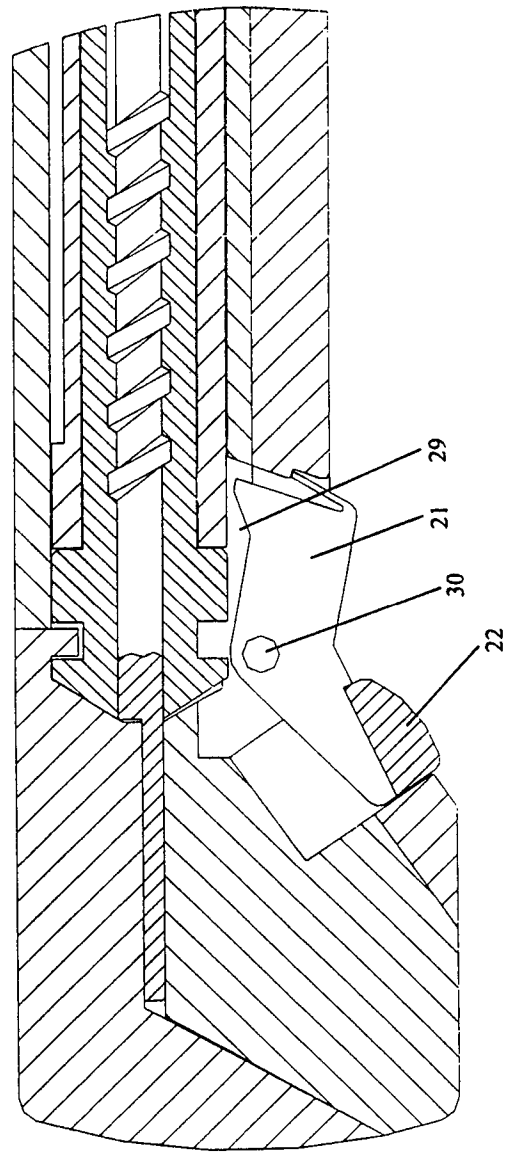


Figure 7



4/7

Figure 8



5/7

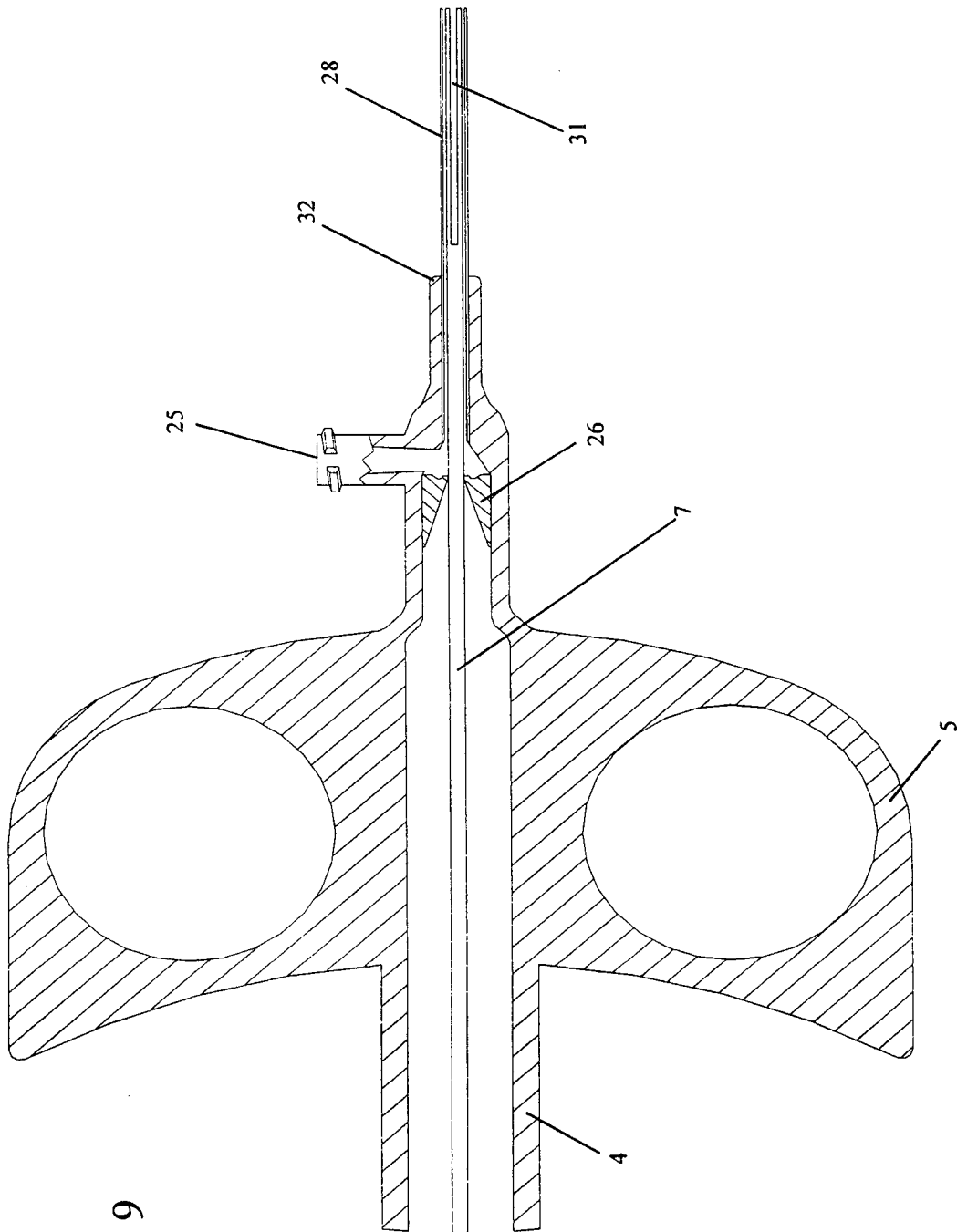
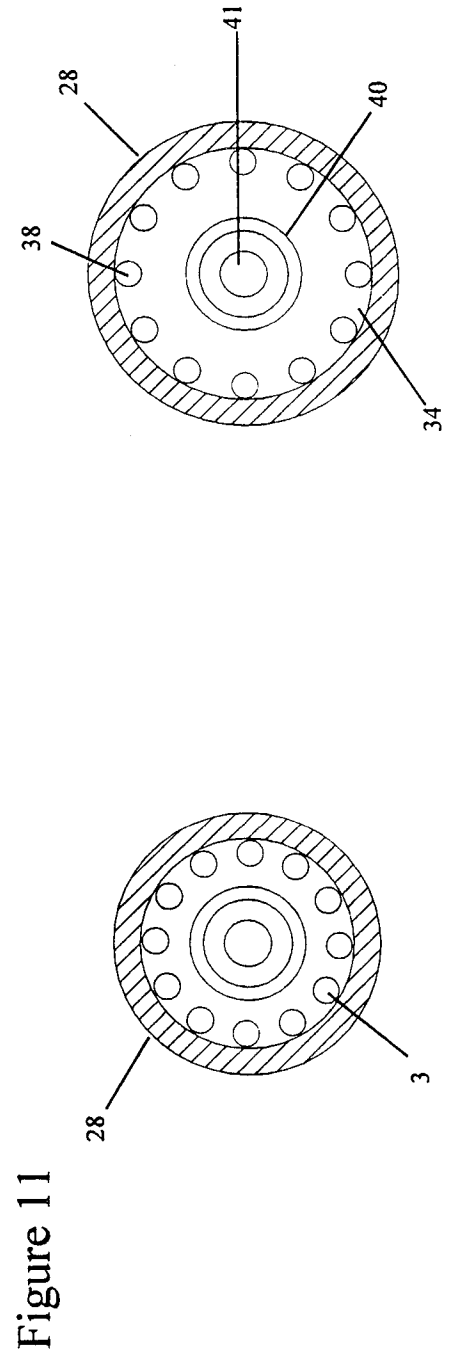
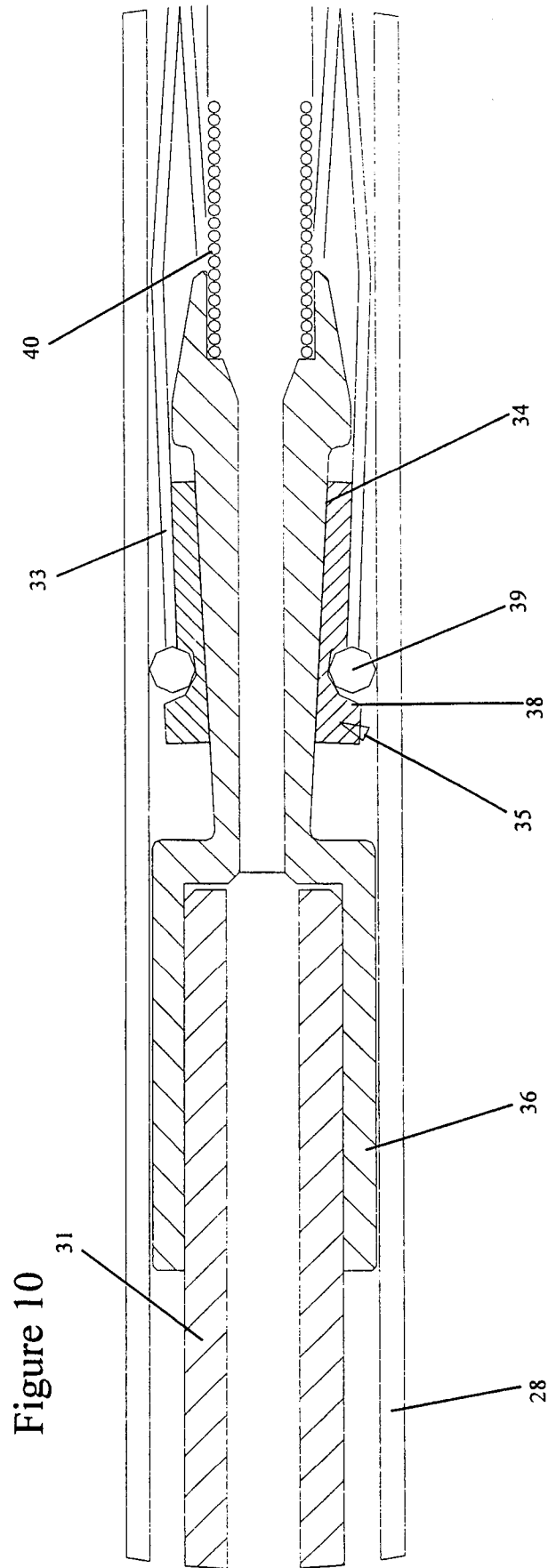


Figure 9

6/7



7/7

Figure 12

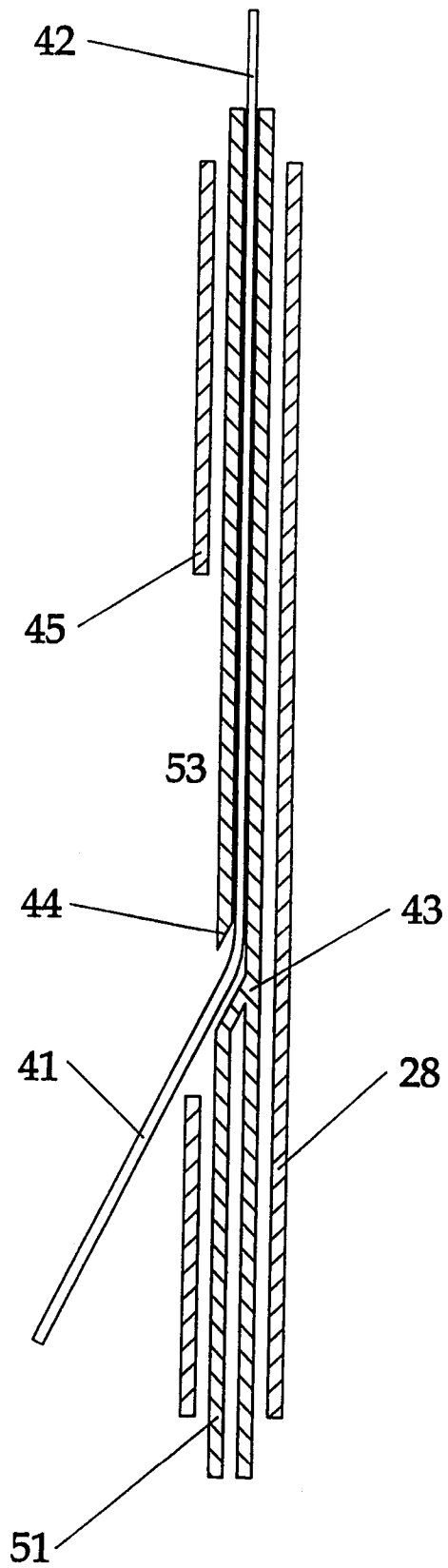
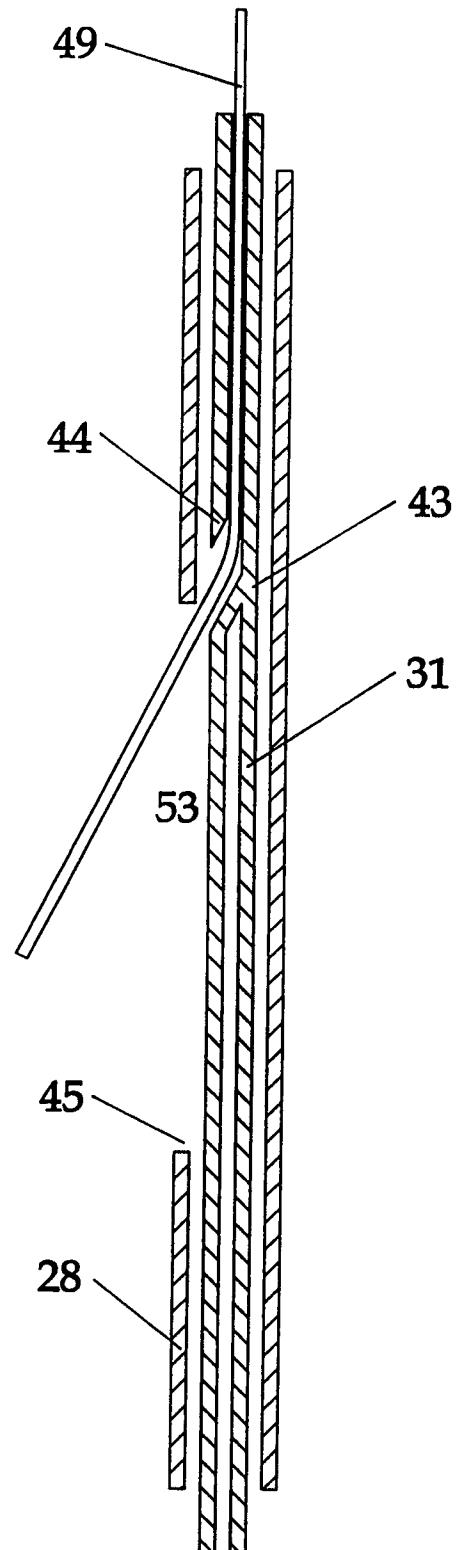


Figure 13



A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 518 838 A (AMS MEDIVENT S.A.) 16 December 1992 see the whole document ---	1,2,5,11
A	US 5 160 341 A (BRENNEMAN ET AL) 3 November 1992 -----	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *Z* document member of the same patent family

Date of the actual completion of the international search

21 July 1998

Date of mailing of the international search report

04.08.98

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Smith, C

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 518838 A	16-12-1992	SE 503249 C AT 128849 T AU 650542 B AU 1823592 A CA 2071120 A DE 9207942 U DE 69205340 D DE 69205340 T ES 2078021 T IE 69545 B JP 6197984 A SE 9101841 A US 5591172 A US 5759186 A	29-04-1996 15-10-1995 23-06-1994 17-12-1992 15-12-1992 26-11-1992 16-11-1995 18-04-1996 01-12-1995 18-09-1996 19-07-1994 15-12-1992 07-01-1997 02-06-1998
US 5160341 A	03-11-1992	NONE	

INTERNATIONAL SEARCH REPORT

Int. l. application No.
PCT/GB 98/01440

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 15
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.